

Message Text

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41

ORIGIN HEW-06

INFO OCT-01 NEA-10 ISO-00 OES-06 COME-00 L-03 /026 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

NEA/IRN:BMORTON (INFO)

----- 081812

P 172044Z SEP 76

FM SECSTATE WASHDC

TO AMEMBASSY TEHRAN PRIORITY

UNCLAS STATE 230952

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, IR

SUBJECT: UNRELIABLE RESULTS OF DIAGNOSTIC PRODUCT
(RADIONUCLIDE) RECALL NO. D-493-6

1. FDA ADVISES OF THE FOLLOWING DIAGNOSTIC PRODUCT RECALL

PRODUCT INVOLVED: TC99M LUNGAGGREGATE REAGENT (TC99M AGGREGATED HUMAN ALBUMIN) KITS. EACH KIT CONTAINS 5 AMPULS OF LUNGAGGREGATE REAGENT (EACH AMPUL CONTAINS 2 ML OF A STERILE SUSPENSION OF AGGREGATED ALBUMIN (HUMAN); FIVE MIXING VIALS, FIVE MIXING VIAL LABELS; FIVE RECORD LABELS AND ONE PACKAGE INSERT. LUNG AGGREGATE REAGENT IS INJECTED INTRAVENOUSLY FOR IMAGING OF REGIONAL PULMONARY PERFUSION IN THE PRESENCE OF CLINICALLY SUSPECTED REGIONAL PULMONARY ISCHEMIA, SUCH AS IS SEEN WITH PULMONARY EMBOLI, NEOPLASMS AND OBSTRUCTIVE LUNG DISEASES. THE PRODUCT MAY BE USED ONLY BY PHYSICIANS LICENSED FOR THE USE OF RADIOACTIVE DRUGS.

PRODUCT IDENTIFICATION: TC99M LUNG AGGREGATE REAGENT LOT NOS. 99.4-196, -197, -198, AND -199 ARE UNDER RECALL. 99 REFERS TO THE PERTINENT RADIONUCLIDE (SODIUM PERTECHNETATE)
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TC-99M); FOUR IDENTIFIES THE PRODUCT AS LUNG AGGREGATE

REAGENT. THE FINAL NUMBER REFERS TO THE CONSECUTIVE LOT

NUMBER OF THE PRODUCT. THE PRODUCT BEARS THE MANUFACTURER
NUMBER OF THE PRODUCT. THE PRODUCT BEARS THE MANUFACTURER
NAME, AND ADDRESS ON THE PACKAGE LABEL.

MANUFACTURER/RECALLING FIRM: MEDI-PHYSICS, INCORPORATED
5801 CHRISTIE AVENUE
EMERYVILLE, CALIFORNIA 94608

2. REASON FOR RECALL: MEDIPHYSICS INCORPORATED (MPI)
RECEIVED SEVERAL COMPLAINTS FROM CUSTOMERS ABOUT THE "TAG-
GING EFFICIENCY" OF THE PRODUCT. MPI THEN SUBJECTED THE
SUSPECTED LOT TO THE EXAMINATION BY CHROMATOGRAPHY, STANN-
OUS CHLORIDE ANALYSIS, AND IN-VIVO ORGAN DISTRIBUTION
STUDIES. THE TESTS INDICATED THE NEED FOR FURTHER EVAL-
UATION. MPI BELIEVES THAT THE COMPLAINTS ABOUT "TAGGING
EFFICIENCY" ARE A RESULT OF AN INCREASED AMOUNT OF UNBOUND
TC-99M IN THE MIXED REAGENT. IN THE PRESENCE OF OXIDANTS
SOME OF THE STANNOUS CHLORIDE IS NOT AVAILABLE TO REDUCE
THE ADDED SODIUM PERTECHNETATE TC-99M THEREBY CAUSING AN
INABILITY OF SOME OF THE TC-99M TO BIND TO THE MACROAG-
GRADED ALBUMIN (HUMAN) WHICH, WHEN ADMINISTERED, INTRA-
VENOUSLY, GOES TO THE LUNGS. WHEN THE LABELED PRODUCT
IS INJECTED INTO MAN FOR DIAGNOSTIC PURPOSES, THE BOUND
TC-99M LODGES IN THE ARTERIAL CAPILLARY BED IN THE LUNGS
AND THE UNBOUND TC-99M IS DISTRIBUTED TO OTHER AREAS OF
THE BODY. THE INCREASED UNBOUND TC-99M MAY CREATE A
"BACKGROUND" PROBLEM WHEN THE LUNGS ARE IMAGED. THE
PHYSICIAN MAY THEN OBTAIN INADEQUATE IMAGES. WHEN THE
PHYSICIAN, IN HIS OPINION, OBTAINS AN INADEQUATE IMAGE,
HE USUALLY REPEATS THE STUDY AND OBTAINS THE NEEDED DIAG-
NOSTIC INFORMATION. THE REAGENT IS NOT TOXIC AS A RESULT
OF THE PRESENCE OF UNBOUND SODIUM PERTECHNETATE TC-99M.
IT APPEARS THAT THE CAUSE OF THE OXIDATION IN THE REAGENT
MAY HAVE BEEN INCOMPLETE REMOVAL OF OXYGEN (AIR) FROM THE
HEAD SPACE OF THE AMPULS DURING FILLING OF SOME OF THE
AMPULS IN THESE LOTS.

3. POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEE TO
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DETERMINE WHETHER THEY HAVE RECEIVED RECALL LETTER FROM
MEDIPHYSICS. ANY QUESTIONS CONSIGNEE MAY HAVE REGARDING
THIS RECALL AND DISPOSITION OF EFFECTIVE LOTS SHOULD BE
DIRECTED TO THE FIRM ATTENTION DR. JOSEPH GOLDSTEIN OR
DR. H. S. WINCHELL.

4. FOREIGN CONSIGNEE AS FOLLOWS:
JEORGIANY HOSPITAL

TEHRAN, IRAN

RECEIVED 2 KITS, NOS. 99.4-196, DATED 7/12/76 ROBINSON

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 17 SEP 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
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From: STATE
Handling Restrictions: n/a
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ISecure: 1
Legacy Key: link1976/newtext/t19760947/aaaabnum.tel
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Review Authority: vandyklc
Review Comment: n/a
Review Content Flags:
Review Date: 02 FEB 2004
Review Event:
Review Exemptions: n/a
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Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

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Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: UNRELIABLE RESULTS OF DIAGNOSTIC PRODUCT (RADIONUCLIDE) RECALL NO. D-493-6
TAGS: OGEN, ETRD, EIND, TBIO, IR, MEDIPHYSICS INC, MPI
To: TEHRAN
Type: TE
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